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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,791	06/29/2001	Anders Berkenstam	13425-040001 / 00244-US	8306
23911	7590	12/19/2003	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			NICKOL, GARY B	
		ART UNIT	PAPER NUMBER	
		1642		

DATE MAILED: 12/19/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/896,791	Applicant(s) BERKENSTAM ET AL.
Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 July 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-11 and 13-21 is/are pending in the application.
4a) Of the above claim(s) 1,4-11 and 13-21 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2 is/are rejected.

7) Claim(s) 3 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: _____

Response to Amendment

The Amendment filed July 15, 2003 (Paper No. 22) in response to the Office Action of January 15, 2003 is acknowledged and has been entered.

Claims 1-11, 13-21 are pending.

Claims 1, 4-11, 13-21 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 2-3 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Objection Maintained:

The specification is remains objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 14, line 1). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim 3 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an isolated mammalian IPAS polypeptide encoded by a nucleic acid molecule comprising SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims drawn to complementary nucleic acid sequences encoding functionally equivalent modified forms of IPAS polypeptides which read on allelic variants.

The claims are drawn to isolated polypeptides encoded by nucleic acid molecules that are capable of hybridizing, under stringent hybridization conditions, with nucleotide sequences complementary to the polypeptide-coding region of SEQ ID NO:2 wherein said nucleic acid molecules code for biologically active mammalian IPAS polypeptides or functionally equivalent modified forms thereof. The claims further include isolated polypeptides encoded by nucleic acid

molecules comprising a nucleic acid sequence that is degenerate as a result of the genetic code to a nucleotide sequence of the latter (e.g. SEQ ID NO:2 or any stringent hybridized complements thereof) that code for biologically active mammalian IPAS polypeptides or functionally equivalent modified forms thereof. However, the claims do not require that the encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of encoded polypeptide variants.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide *sufficient* distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the broadly claimed polypeptides include a whole universe of non-coding and or coding polynucleotide fragments. Clearly, it would be expected that a substantial number of the hybridizing or complementary polynucleotides encompassed by the claims **would not** share either structural or functional properties with mammalian IPAS polypeptides. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed.*” (See page 1117.) The specification does not “clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated mammalian IPAS polypeptide encoded by a nucleic acid molecule comprising SEQ ID NO:2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Bradfield *et al.* (WO 99/28464, 10 June 1999).

Bradfield *et al.* teach (see attached sequence listing) an isolated mammalian IPAS polypeptide encoded by:

a) a nucleic acid molecule comprising a nucleotide sequence which is capable of hybridizing, under stringent hybridization conditions, with a nucleotide sequence complementary to the polypeptide-coding region of SEQ ID NO:2 which inherently codes for a biologically active mammalian IPAS polypeptide or functionally equivalent modified form thereof.

b) a nucleic acid molecule comprising a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of the latter of SEQ ID NO:2 or any stringent hybridized complement thereof which codes for a biologically active mammalian IPAS polypeptide or functionally equivalent modified form thereof.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

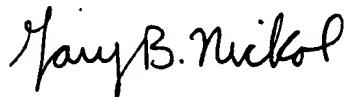
Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 12, 2003



Page 3

CC cDNA (see AAX5896) was identified in a search of murine ESTs design CC to identify bHLH-PAS proteins, and by RACE amplification of lung CC cDNA. MOP7 was characterised as hypoxia inducible factor 3 alpha CC (HIF 3 alpha). Its expression profile is distinct from that of CC HIF 1 alpha (see AAY0289), HIF 2 alpha (see AAY06290), MOP3 (see AAY06291). An receptor and An receptor nuclear translocator (ARN), CC suggesting a different functional role. MOP7 probably regulates CC the same genes as HIF 1 alpha and 2 alpha, as evidenced by its CC dimerisation with the same partners (ARNT, MOP3) and recognition CC of the same core response element. MOP7 may have a functional CC role associated with response to low oxygen in the tissues in CC which it is expressed. The invention provides novel MOPs 2-9 CC nucleic acids (see AAX5891-88) and Proteins (see AAY06289-97). CC These are useful in a variety of research, diagnostic and CC therapeutic applications. Several of the MOPs are alpha-class CC hypoxia inducible factors. Others are involved in circadian signal CC transduction.

Y	688	CTCTCGCTCGGAGCTCCCGTCAATGCCCTGGCTATCTGTTGACCATCCCC-----	741
X	1	1 1 1 1 1 1 1 1 1	
X	208	ProArgSerGluProProLeuGlnCysLeuValleuLeuCysGluAlaIleProHisPro	227
T	742	-----CAGTCCCCCTCACGATGGCTACTG	771
X	228	;;: 1 1 1 1 1AlaserLeuGluProProLeuGlyArgGlyAlaPheLeu	240
RESULT 3			
X	4893326		
D	AAB93326	standard; Protein: 632 AA.	
X	AAB93326;		
C			
T	26-JUN-2001	(first entry)	

XX
SQ Sequence 662 AA;
Lignment Scores:
Med. NO.: 2.03e-85
Score: 1045.00
Percent Similarity: 85.88%
Best Local Similarity: 85.49%
Query Match: 51.99%
DB: 20
Length: 662
Matches: 218
Conservative: 1
Mismatches: 5
Indels: 31
Gaps: 3
US-09-896-791B-2 (1-1100) x AAV06295 (1-662)